## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Atty. Docket No.:

161765.00520

(01113/US)

Anurag RATHORE et al.

Serial No.:

10/646,798

Group Art Unit:

1626

Filed:

August 25, 2003

Examiner:

**TBA** 

For:

Method for the Preparation of Growth Hormone and Antagonist Thereof

Having Lower Levels of Isoform Impurities Thereof

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. §§ 1.56(a), 1.97 and 1.98 et seq., Applicants submit herewith the attached Form PTO/SB/08A. The listed documents were cited in the specification of the application. Applicants have submitted herewith a copy each of the references cited on the attached Form PTO/SB/08A except for the U.S. patents. Applicants respectfully request that the Examiner consider and enter all the documents cited on the enclosed Form PTO/SB/08A into the file of the above-identified application. Applicants also request an indication of the same by return of the Form PTO/SB/08A being initialed and dated by the Examiner.

No fees are believed due to ensure consideration of the attached documents by the Examiner. However, if any fees are required or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 19-0733, as necessary.

Respectfully submitted,

Date: April 21, 2004

By:

Ajay Pathak

Registration No. 38,266

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Attachments:

Form PTO/SB/08A References Cited on Form PTO/SB/08A

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE U.S. DEPARTMENT OF COMMERCE U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO				Complete if Known			
INFORMATION DISCLOSURE				Application Number	10/646,798		
STATEMENT BY APPLICANT				Filing Date	August 25, 2003		
			i i Liomiti	First Named Inventor	Anurag RATHORE et al.		
				Group Art Unit	1626		
(use as many sheets as necessary)				Examiner Name	TBA		
Sheet	1	of	1	Attorney Docket Number	161765.00520 (01113/US)		

	U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant	
Initials *	No.1	Number - Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Cited Doddinerit	Passages or Relevant Figures Appear	
		US-5,849,535	12/15/1998	Cunningham et al.		
		US- 6,057,292	05/02/2000	Cunningham et al.		
		US-	-			
		US-				

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ <sup>¢</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Applicant of Cited  Document		
		WO 96/02570	02/01/96			<u>-</u>
		WO 02/27478	07/25/02			
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	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>			
		Andersson et al., "Isolation and characterization of a trisulfide variant of recombinant human growth hormone formed during expression in <i>Escherichia coli</i> ," Int. J. Peptide Protein Res. 47:311-321 (1996).				
		J. Houk and G.M. Whitesides, "Structure-Reactivity Relations for Thiol-Disulfide Interchange," J. M. Chem. Soc., 109:6825-6836 (1987).				
		A. Jesperson et al., "Characterisation of a trisulphide derivative of biosynthetic human growth hormone produced in <i>Escherichia coli</i> ," Eur. J. Biochem. 219:365-373 (1994).				
		Jorgensen et al., "Quantifying biosynthetic human growth hormone in <i>Escherichia coli</i> with electrophoresis under hydrophobic conditions," J. Chromatography A 817:205-214 (1998).				
		The Merck Index, 12 <sup>th</sup> Edition, S. Budavari (Editor), Merck & Co., Inc., Therapeutic Category and Biological Activity Index, p. THER-19 (under "CHELATING AGENT"), Whitehouse Station, NJ (1996).				

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Examiner Signature		Date Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1460, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450.

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <u>www.uspto.gov</u> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.